

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Howard Bernstein, Yan Zhang, M. Amin Khan and Mark A. Tracy

Application No.: 10/039,285 Group Art Unit: 1615

Filed: January 3, 2002 Examiner: Not assigned

Title: Modulated Release From Biocompatible Polymers

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202	
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Date	Wendy Morrissey
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Wendy Morrissey	
Typed or printed name of person signing certificate	

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
P.O. Box 2327  
Arlington, VA 22202

Sir:

This Information Disclosure Statement is submitted:

under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)

under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

under 37 CFR 1.97(c) together with either:  
 a Statement under 37 CFR 1.97(e), as checked below, or  
 a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

under 37 CFR 1.97(d) together with:  
 a Statement under 37 CFR 1.97(e), as checked below, and  
 a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Enclosed herewith is form PTO-1449:

- Copies of the cited references are enclosed.
- All copies of the cited references have been entered in prior U.S. Application Nos. 09/274,613, 09/056,566, 08/237,057 and 08/727,531, to which priority under 35 U.S.C. 120 is claimed. Please see the earlier applications for a copy of any cited references.
- The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
  - the explanation provided on the attached sheet.
  - the explanation provided in the Specification.
  - submission of the enclosed International Search Report.
  - submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
  - the enclosed English language abstract.

[ ] Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

Examiner

Date

[ ] A copy of each above-cited application, including the current claims, is enclosed.

[ ] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

[ ] A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.

[ ] Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.

[X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated:

*May 21, 2002*

PTO-1449 REPRODUCED		ATTORNEY DOCKET NO. 1733.1003-010	APPLICATION NO. 10/039,285
<p style="text-align: center;"><b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b></p> <p style="text-align: center;">May 21, 2002</p> <p style="text-align: center;">(Use several sheets if necessary)</p>		APPLICANT Howard Bernstein, et al.	
		FILING DATE January 3, 2002	GROUP 1615

## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,675,189	06/23/87	Kent, J.S. et al.	424	490	
	AB	4,962,091	10/09/90	Eppstein, D.A. et al.	514	2	
	AC	3,523,906	08/11/70	Vrancken, M.N. et al.	252	316	
	AD	3,691,090	09/12/72	Kitajima, M. et al.	252	316	
	AE	3,737,337	06/05/73	Schnoring, H. et al.	117	100	
	AF	3,887,699	06/03/75	Yolles, S.	424	19	
	AG	4,389,330	06/21/83	Tice, T.R. et al.	427	213.36	
	AH	4,530,840	07/23/85	Tice, T.R. et al.	514	179	
	AI	4,542,025	09/17/85	Tice, T.R. et al.	424	78	
	AJ	4,835,139	05/30/89	Tice, T.R. et al.	514	15	
	AK	4,891,225	01/02/90	Langer, R.S. et al.	424	428	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL	WO91/12882	05/09/91	PCT			
	AM	WO96/07399A1	14/03/96	PCT			
	AN	WO93/07861	29/04/93	PCT			
	AO	WO93/25221	23/12/93	PCT			
	AP	WO90/09166	23/08/90	PCT			
	AQ	WO90/13780	15/11/90	PCT			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AR	Pratt, L., et al., "The Effect of Ionic Electrolytes on Hydrolytic Degradation of Biodegradable Polymers: Mechanical and Thermodynamic Properties and Molecular Modeling," <i>J. Polymer Science</i> 31(7):1759-1769 (1993).
AS	Costantino, H. R., et al., "Solid-Phase Aggregation of Proteins under Pharmaceutically Relevant Conditions," <i>J. of Pharmaceutical Sciences</i> , 83(12):1662-1669 (1994).
AT	Costantino, H. R., et al., "Moisture-Induced Aggregation of Lyophilized Insulin," <i>Pharmaceutical Research</i> , 11(1):21-29 (1994).

EXAMINER

DATE CONSIDERED

<p>PTO-1449 REPRODUCED MAY 28 2002 INFORMATION DISCLOSURE CITATION IN AN APPLICATION May 21, 2002 (Use several sheets if necessary)</p> <p style="text-align: center;">U. S. PATENT DOCUMENTS</p>				ATTORNEY DOCKET NO. 1733.1003-010		APPLICATION NO. 10/039,285	
				APPLICANT Howard Bernstein, et al.			
				FILING DATE January 3, 2002		GROUP 1615	
EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA2	3,891,570	06/24/75	Fukushima, M. et al.	252	316	
	AB2	4,391,797	07/05/83	Folkman, M.J. et al.	424	19	
	AC2	5,176,907	01/05/93	Leong, K.W.	424	78.08	
	AD2	5,122,367	06/16/92	Ron, E. et al.	424	80	
	AE2	5,145,674	09/08/92	Lane, G.A. et al.	424	78.08	
	AF2	4,711,782	12/08/87	Okada, H. et al.	424	455	
	AG2	5,126,147	06/30/92	Silvestri, L.J. et al.	424	497	
	AH2	5,192,741	03/09/93	Orsolini, P. et al.	514	4	
	AI2	4,732,889	03/22/88	Cynshi, O. et al.	514	8	
	AJ2	4,879,272	11/07/89	Shimoda, N. et al.	514	8	
	AK2	4,992,419	02/12/91	Woog, H. et al.	514	8	
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES      NO
	AL2	WO92/11844	23/7/92	PCT			
	AM2	WO95/29664 A1	09/11/95	PCT			
	AN2	WO94/12158	09/06/94	PCT			
	AO2	0633 020 A1	11/01/95	EPO			
	AP2	WO93/17668	16/09/93	PCT			
	AQ2	WO94/07469	04/14/94	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AU	Costantino, H.R., et al., "Aggregation of a Lyophilized Pharmaceutical Protein, Recombinant Human Albumin: Effect of Moisture and Stabilization by Excipients," <i>Biotechnology</i> , 13:493-496 (1995).					
	AV	Creighton, T.E., "Physical Forces That Determine the Properties of Proteins," <i>In Proteins, Structures and Molecular Principles</i> , (NY: W.H. Freeman and Company), pp. 149-150.					
	AW	Cunningham, B. C., et al., "Dimerization of Human Growth Hormone by Zinc," <i>Science</i> , 253:545-548 (August 1991).					
EXAMINER				DATE CONSIDERED			

PTO-1449 REPRODUCED  INFORMATION DISCLOSURE CITATION IN AN APPLICATION  May 21, 2002  (Use several sheets if necessary)		ATTORNEY DOCKET NO. 1733.1003-010	APPLICATION NO. 10/039,285
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## U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA3	4,853,218	08/01/89	Yim, Z. et al.	424	85.7	
	AB3	4,235,236	11/25/80	Theeuwes, F.	128	260	
	AC3	4,906,474	03/06/90	Langer, R.S. et al.	424	428	
	AD3	5,019,400	5/28/91	Gombotz, W.R. et al.	424	497	
	AE3	4,981,696	1/1/91	Loomis, G.L. et al.	424	486	
	AF3	4,637,905	1/20/87	Gardner, D.L.	264	4.3	
	AG3	4,897,268	1/30/90	Tice, T.R. et al.	424	422	
	AH3	4,767,628	8/30/88	Hutchinson, F.G.	424	426	
	AI3	3,928,566	12/23/75	Briggs, A.R. et al.	424	94	
	AJ3	4,166,800	9/4/79	Fong, J.W.	252	316	
	AK3	4,530,901	7/13/85	Weissmann, C.	435	70	

## FOREIGN PATENT DOCUMENTS

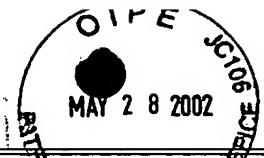
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL3	0580 428 A1	01/26/94	EPO			
	AM3	0537559 A1	21/04/93	EPO			
	AN3	0266119 A3	04/05/88	EPO			
	AO3	0330180 A1	30/08/89	EPO			
	AP3	WO89/03678	05/05/89	PCT			
	AQ3	WO90/13285	15/11/90	PCT			

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

AX	Sato, Toyomi, et al., "Porous Biodegradable Microspheres for Controlled Drug Delivery. I. Assessment of Processing Conditions and Solvent Removal Techniques," <i>Pharmaceutical Research</i> , 5(1):21-29 (1988).
AY	Langer, R., "New Methods of Drug Delivery," <i>Science</i> , 249:1527-1533 (September 1990).
AZ	Liu, W. R., et al., "Moisture-Induced Aggregation of Lyophilized Proteins in the Solid State," <i>Biotechnology and Bioengineering</i> , 37:177-184 (1991).
AR2	Lu, W., and Park, T. G., "Protein Release from Poly(lactic-co-glycolic acid). Microspheres: Protein Stability Problems," <i>PDA J. of Pharmaceutical Science &amp; Technology</i> , 49(1):13-19 (Jan-Feb 1995).

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DATE CONSIDERED



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EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA4	4,871,538	10/02/89	Yim, Z. et al.	424	85.7	
	AB4	B1 4,985,404	04/21/92	Mitchell, J.W.	514/6	514/2	
	AC4	4,655,777	04/07/87	Dunn, R.L., et al.	623	16	
	AD4	5,075,115	12/24/91	Brine, C.J.	424	486	
	AE4	5,344,654	09/06/94	Rueger, D.C., et al.	424	423	
	AF4	4,237,114	12/02/80	Cardarelli, N.F.	424	78	
	AG4	4,806,524	02/21/89	Kawaguchi, T., et al.	514	8	
	AH4	4,252,791	02/24/81	Grossberg, S.E., et al.	424	85	
	AI4	5,441,734	08/15/95	Reichert, P., et al.	424	85.7	
	AJ4	5,413,797	05/09/95	Khan, M.A., et al.	424	489	
	AK4						
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
	AL4	0 595 030 A2	05/09/91	PCT			
	AM4	WO93/02712	18/02/93	PCT			
	AN4	WO95/11010	27/04/95	PCT			
	AO4	WO94/19373 A1	01/09/94	PCT			
	AP4	0 307 097 A2	15/03/89	EPO			
	AQ4	WO91/18927 A1	12/12/91	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AS2	Cohen, S., et al., "Controlled Delivery Systems for Proteins Based on Poly(Lactic/Glycolic Acid) Microspheres," <i>Pharmaceutical Research</i> , 8(6):713-720 (1991).					
	AT2	Hora, M.S. et al., "Release of Human Serum Albumin from Poly(lactide-co-glycolide) Microspheres," <i>Pharmaceutical Research</i> , 7(11):1190-1194 (1990).					
	AU2	Hageman, M.J., et al., "Preformulation Studies Oriented Toward Sustained Delivery of Recombinant Somatotropins," <i>J. Agric. Food Chem.</i> , 40:348-355 (1992).					
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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES      NO
	AL5	0 123 291 A2	31/10/84	EPO			
	AM5	0 281 299 A1	07/09/88	EPO			
	AN5	0 251 680 A2	07/01/88	EPO			
	AO5	WO92/19226	12/11/92	PCT			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AV2	Cleland, J. L., et al., "Characterization of Recombinant Human Growth Hormone-PLGA Formulations in Animals," Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22:143-144 (1995).					
	AW2	Cleland, J. L., et al., "One Month Continuous Release Recombinant Human Growth Hormone-PLGA Formulations," Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22:149-150 (1995).					
	AX2	Mullerad, J., et al., "Delivery of IL-1 Microspheres to Tumor Macrophages," Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22:512-513 (1995).					
	AX2	Cleland, J. L., et al., "In Vitro Release of Bioactive Recombinant Human Interferon- $\gamma$ From PLGA Microspheres," Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22:518-519 (1995).					
	AR2	Park, T. G., et al., "Importance of In Vitro Experimental Conditions on Protein Release Kinetics, Stability and Polymer Degradation in Protein Encapsulated Poly(D, L-Lactic Acid-Co-Glycolic Acid) Microspheres," J. of Controlled Release, 33:211-222 (1995).					
	AS2	Nagata, S., et al., "Synthesis in E. Coli of a Polypeptide with Human Leukocyte Interferon Activity," Nature, 284:316-320 (March 1980).					
	AT2	Rubinstein, M., "The Structure of Human Interferons," Biochimica et Biophysica Acta., 695:5-16 (1982).					
	AU2	Sah, H., et al., "The Influence of Biodegradable Microcapsule Formulations on the Controlled Release of a Protein," J. of Controlled Release 30:201-211 (1994).					
EXAMINER			DATE CONSIDERED				

